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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,193	03/25/2002	Jean-Pierre Molitor	H 4157 PCT/US	1128
23657	7590	03/21/2006	EXAMINER	
COGNIS CORPORATION PATENT DEPARTMENT 300 BROOKSIDE AVENUE AMBLER, PA 19002			MARX, IRENE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/980,193

Applicant(s)

MOLITOR ET AL.

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 23-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

The amendment filed 1/25/06 is acknowledged.

Claims 12-22 are being considered on the merits.

Claims 23-35 are withdrawn from consideration as directed to a non-elected invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-22 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Inlow *et al.* taken with Kopp-Holtwiesche (DE 3738812) and Forster *et al.* (WO 95/11660) for the reasons as stated in the last Office action and the further reasons below.

Inlow *et al.* discloses a reaction medium comprising a microemulsion and the microorganisms insect cells wherein the size distribution overlaps and which contains the same ingredients (see, e.g., Example 8, Example 9 and Example 2). The reference differs from the claimed invention a fatty acid methyl ester is not used in the medium. However, Kopp-Holtwiesche discloses a similar microbial reaction medium containing methyl laurate or other fatty acid methyl esters (See, e.g., Examples 1 and 3).

The references differ from the claimed invention in that at least Inlow *et al.* use an animal oil rather than a vegetable oil. However, Forster *et al.* adequately demonstrate that it is routine in this art to use a variety of triglycerides for the production of various emulsions (See, e.g. page 5, last paragraph). The Forster *et al.* reference also discloses the use of two emulsifiers in combination wherein one acts as a coemulsifier (See, e.g., page 8) and various amounts and combinations of these emulsifiers. The emulsions are produced by the "phase inversion temperature" (PIT) method.

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While the compositions of Forster are not explicitly disclosed as being reaction media containing microorganisms, it is well recognized in the art that cosmetic compositions such as those disclosed in the reference are not sterile upon opening and are highly susceptible to microbial degradation. Thus they clearly constitute “a reaction medium” and can reasonably be presumed to contain microorganisms as claimed.

The ranges of ingredient content discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of the amounts used in the reaction medium preparation for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

It is also noted that the composition is claimed as containing a “phase inversion temperature emulsion”, which constitutes claiming as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of *prima facie* obviousness or anticipation for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the reaction medium of Inlow *et al.* by substituting microemulsions containing animal oils with microemulsions containing fatty acid alkyl esters, and methyl esters in particular, as suggested by the teachings of Kopp-Holtwiesche and/or a variety of oils including specific vegetable oils as taught by Forster *et al.* (WO 95/11660), as well as altering the proportions of the various ingredients for optimization purposes for the expected economic benefit of enhancing the bioavailability of the lipids to recalcitrant microbial that will support their growth and proliferation as well as providing the option of not having the filter sterilize the lipid fraction and the rest of the media components separately. The growth and proliferation of recalcitrant microorganism has the expected benefit of increasing the yields of pharmaceutically and industrially important metabolites and/or aiding in the identification of pathogenic microorganisms.

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Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the examples show that relatively large amount of the fatty acid esters present in the microemulsion. However, this is not the claim designated invention.

Regarding the argument that the microemulsion could not be useful as a carbon source or as a substrate, it is noted with all due respect that the claims now specifically comprise at least one of a carbon source or substrate, which is independent of the microemulsion. Therefore this argument is without merit.

Regarding the use of the cosmetic formulation as a fermentation medium, it is noted that the claims are directed to a reaction medium. It is noted that even though Forster *et al.* does not teach that the composition can be used for a fermentation medium, however, the intended use of the composition does not distinguish the composition since such undisclosed use is inherent in the Forster *et al.* composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112). Applicant has not demonstrated that the prior art compositions would not be suitable for fermentation. Regarding the statement that cosmetic compositions generally contain an ingredient which suppresses or eliminates the growth of microorganisms, the rejection is not made over any cosmetic composition. It is not clear that any of the stated ingredients in the specific composition of Forster *et al.* has this property for any and all microorganisms. It is submitted that the medium disclosed in Forster would be suitable for the culturing of a fatty acid

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degrading strain such as the *C. tropicalis* strain disclosed by Kopp-Holtwiesche that degrades at least fatty acid components of triglycerides (See, e.g., Example 3).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In *re* Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In *re* Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, all of the references pertain to the addition of triglycerides or fatty acid alkyl esters to media suitable for culturing microorganisms or for sustaining their growth. It is noted in this regard that at least Inlow *et al.* and Kopp-Holtwiesche are directed to culture media comprising microorganisms.

Note still further that, contrary to applicant's argument, it is well established that motivation for combining references need not come from the references themselves, as long as applicant's disclosure is not improperly used in a hindsight reconstruction of the claimed invention. See *Ex parte Levengood*, 28 USPQ2d 1300 (1993), at 1301. ("Motivation for combining the references need not be explicitly found in the references themselves. Indeed, the examiner may provide an explanation based on logic and sound scientific reasoning that will support a holding of obviousness.")(Citations omitted.)

With respect to applicant's arguments that one of ordinary skill in the art would not have modified the culture medium of Inlow according to the teachings of Kopp-Holtwiesche because lauric acid methyl esters are not part of an emulsion used in the reaction medium. Inasmuch as the amount of emulsion contained in the present culture medium is not disclosed, it is uncertain that all of the medium is emulsified. It is noted that the composition of Kopp-Holtwiesche would have been reasonably expected by one of ordinary skill in the art to be naturally emulsified at least to some extent as a consequence of agitation (See, e.g., Examples). In addition a reaction medium is no more than a composition that supports the growth of a microorganism.

In the instant case, the prior art compositions render obvious the composition as claimed, which requires a microemulsion in terms of product by process of a certain average size.

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The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

No claim is allowed.


**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Irene Marx  
Primary Examiner  
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